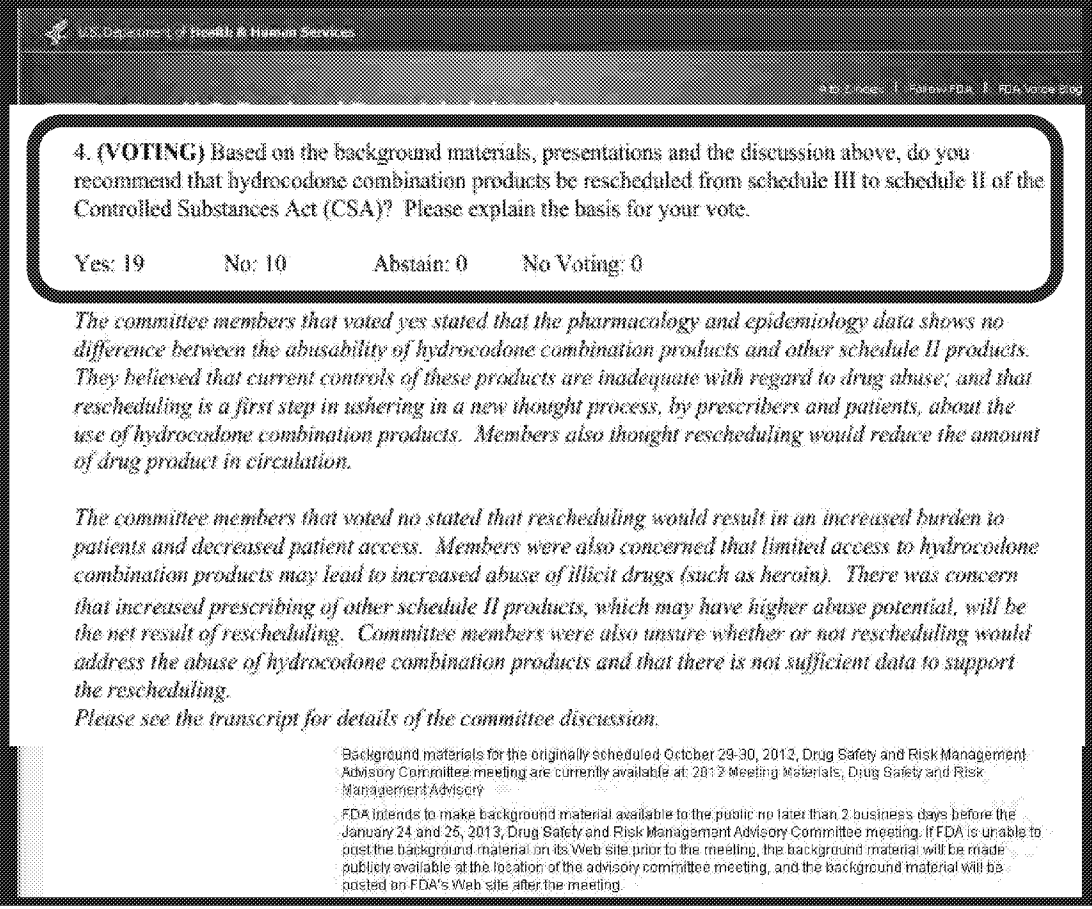
FDA Advisory Committee Votes in Favor of Hydrocodone Rescheduling

On January 25, 2013, the FDA's Drug Safety and Risk Management Advisory Committee voted yes (19-10) to recommend rescheduling of hydrocodone from Schedule III to Schedule II



U.S. Department of Health & Human Services

4. **(VOTING)** Based on the background materials, presentations and the discussion above, do you recommend that hydrocodone combination products be rescheduled from schedule III to schedule II of the Controlled Substances Act (CSA)? Please explain the basis for your vote.

Yes: 19 No: 10 Abstain: 0 No Voting: 0

The committee members that voted yes stated that the pharmacology and epidemiology data shows no difference between the abusability of hydrocodone combination products and other schedule II products. They believed that current controls of these products are inadequate with regard to drug abuse; and that rescheduling is a first step in ushering in a new thought process, by prescribers and patients, about the use of hydrocodone combination products. Members also thought rescheduling would reduce the amount of drug product in circulation.

The committee members that voted no stated that rescheduling would result in an increased burden to patients and decreased patient access. Members were also concerned that limited access to hydrocodone combination products may lead to increased abuse of illicit drugs (such as heroin). There was concern that increased prescribing of other schedule II products, which may have higher abuse potential, will be the net result of rescheduling. Committee members were also unsure whether or not rescheduling would address the abuse of hydrocodone combination products and that there is not sufficient data to support the rescheduling.
Please see the transcript for details of the committee discussion.

Background materials for the originally scheduled October 29-30, 2012, Drug Safety and Risk Management Advisory Committee meeting are currently available at: 2012 Meeting Materials, Drug Safety and Risk Management Advisory

FDA intends to make background material available to the public no later than 2 business days before the January 24 and 25, 2013, Drug Safety and Risk Management Advisory Committee meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting.

FDA Recommends Hydrocodone Up-Scheduling

www.newsday.com/news/nation/fda-recommends-stricter-painkiller-rules-1.6316243

Newsday is shocked the Islanders traded Matt Moulson for Thomas Vanek.

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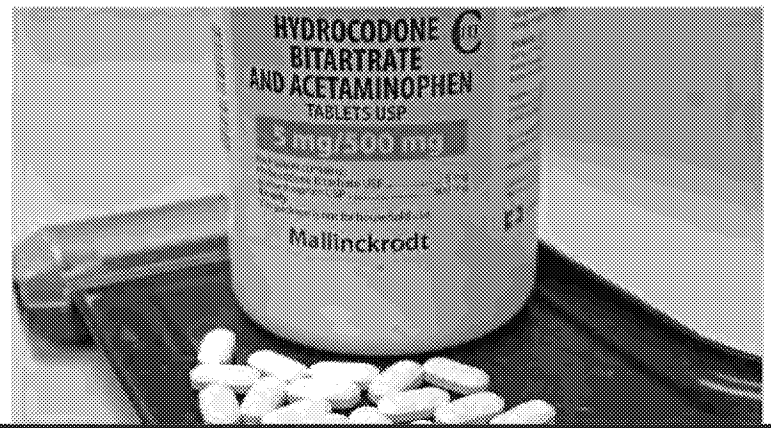
FDA recommends stricter painkiller rules

Originally published: October 24, 2013 7:31 PM
Updated: October 24, 2013 10:19 PM
By KEVIN DEUTSCH kevin.deutsch@newsday.com



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Source: www.newsday.com, October 24, 2013

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control

FDA Approves Pure Hydrocodone Pain Killer

www.examiner.com/article/new-narcotic-pain-pill-zohydro-pure-hydrocodone-pain-killer-approved-by-fda

examiner.com

New narcotic pain pill Zohydro: Pure hydrocodone pain-killer approved by FDA

See also Top News / Hydrocodone / Oxycodone

October 27, 2013

Zohydro, a pure hydrocodone pain pill, has just been approved for sale in the U.S. by the FDA. This pure hydrocodone pill will be classified as a Schedule II drug, much like Oxycontin and oxycodone, according to "Fox and Friends Weekend" on Sunday Oct. 27.

According to **Bloomberg** on Oct. 25, Hydrocodone is the narcotic pain medication found in pain pills like Vicodin

Next article

Crypto Locker virus locks your computer files until you pay ransom

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Popular Videos

Annually 1,500 Children Are Treated in ERs For Pain Medicine ODs

Source: www.examiner.com, October 27, 2013

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control

Oxycodone

- OxyContin controlled release formulation of Schedule II oxycodone
  - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
  - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
  - 10, 15, 20, 30, 40, 60, 80mg available

- Effects:
  - Similar to morphine in effects and potential for abuse/ dependence
  - Sold in "Cocktails" or the "Holy Trinity" (Oxycodone, Soma ® / carisoprodol, Alprazolam / Xanax®)

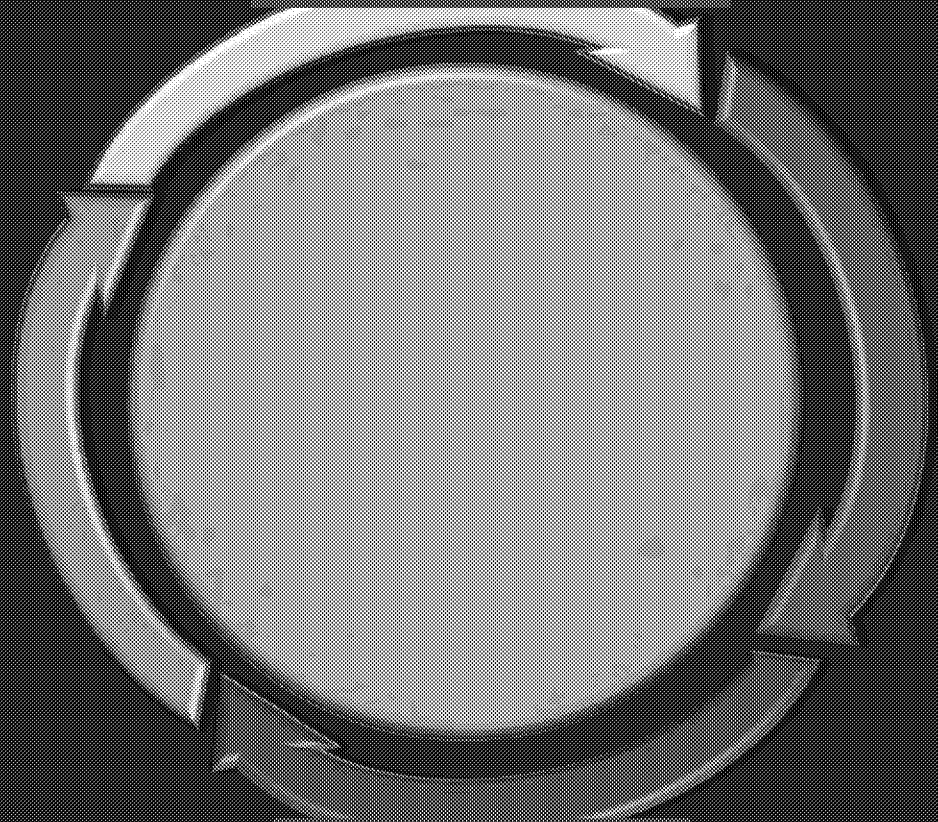
- Street price: Approx. $80 per 80mg tablet

NOTE: New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.

Heroin (& Prescription Drugs)

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control

Circle of Addiction & the Next Generation



Oxycodone Combinations
Percocet®
$7-$10/tab

OxyContin®
$80/tab

Roxicodone®
Oxycodone IR
15mg, 30mg
$30-$40/tab

Heroin
$15/bag

Hydrocodone
Lorcet®
$5-$7/tab

HEROIN: NO LONGER CONFINED TO URBAN AREAS

More suburban teens turning from pills to heroin, authorities say

By Ed Fletcher
McClatchy Newspapers

Tuesday, April 3, 2012

Photo by Randy Pench/Sacramento Bee/MCT — Brandon Scott, 19, of Auburn, Calif., leads a workshop at the Auburn Library regarding drugs and how they affect teens. Brandon transitioned from RX to heroin but has since gone through the Full Circle Treatment Center program and has been clean for about two years.

SACRAMENTO, Calif. – Heroin, a drug most often associated with the gritty back alleys of big cities, is making a surprising surge in suburban, affluent places.

Many new heroin addicts started as teens, abusing prescription painkillers they found in their homes, say law enforcement and public health officials.

HEROIN: NO LONGER CONFINED TO URBAN AREAS

trafficking heroin, cocaine and other drugs in the District and Montgomery and Prince George's counties.

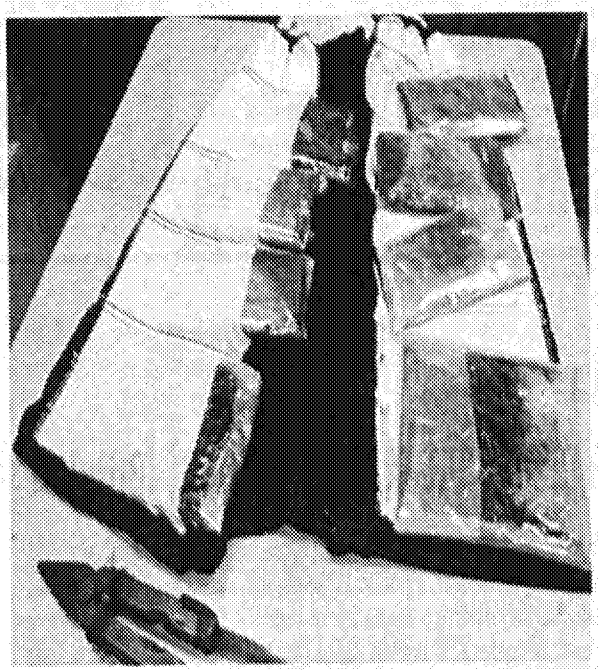
About 4.2 percent of Maryland high school students reported trying heroin at least once in a 2011 statewide survey, up from 2.4 percent in 2007.

Former heroin addict Mike Gimbel has spent the past three decades working on substance abuse education and treatment in Maryland. He called the suburban heroin shift a "big-time trend" in the Washington area and elsewhere.

"Instead of waiting for the suburban kids to come into the city, the dealers have gone out to the suburbs," he said. "It just blows away these parents in the middle-class communities — the last drug in the world they think their kids are going to use is heroin."

The resurgence is tied to the booming market for prescription painkillers like OxyContin and Vicodin — experts say painkiller abusers often move on to heroin due to its availability and their craving for a stronger high.

Beth Kane Davidson, director of the Addiction Treatment Center at Suburban Hospital in Bethesda,



EXAMINER FILE

Montgomery and Fairfax counties have both reported spikes in heroin use.

> *"Instead of waiting for the suburban kids to come into the city, the dealers have gone out to the suburbs. It just blows away these parents in the middle-class communities — the last drug in the world they think their kids are going to use is heroin."*
>
> - **Mike Gimbel**, former heroin addict

Getting high

Percentage of Maryland high schoolers who reported using heroin:

	2011	2009	2007	2005
Males	5.7	5.8	3.7	2.8
Females	1.9	1.7	0.8	2.3
Total	4.2	4.1	2.4	2.6

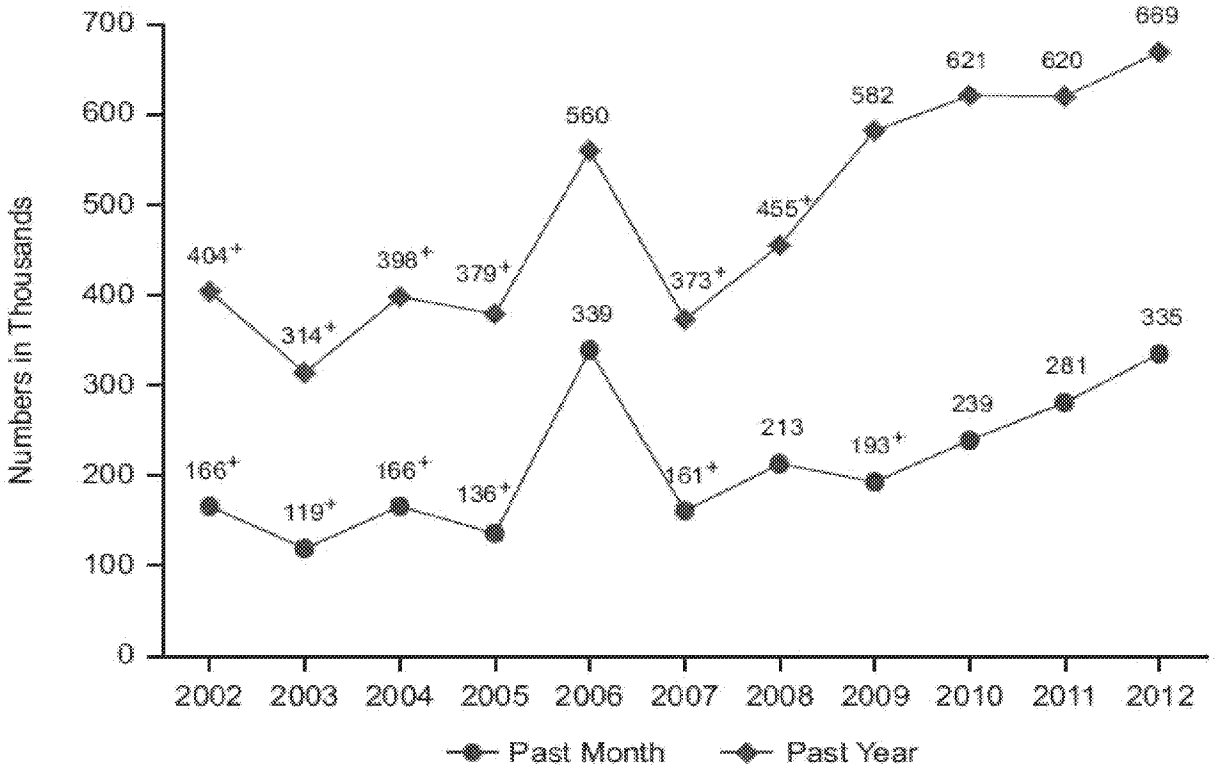
SOURCE: MARYLAND YOUTH RISK BEHAVIOR SURVEY

said. "And then there were times when I thought I was living in hell."

Dan Torsch died of a heroin overdose at age 24 in December 2010. Since then, his mother set up GRASP, an organization for grieving family members to connect after losing a loved one to substance abuse, along with a foundation in Dan's name to help families pay for addiction treat-

Past Month & Year Heroin Use – Ages 12 or Older (2002 – 2012)

Figure 2.4 Past Month and Past Year Heroin Use among Persons Aged 12 or Older: 2002-2012



+ Difference between this estimate and the 2012 estimate is statistically significant at the .05 level.

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)

Example: "Heroin a Growing Problem in St. George"

- St. George, Utah is known as a good place to raise a family or to retire, but aside from the wholesome image, it's fighting a newfound heroin problem.

- Police point to users like Karli Chambers: 27 year-old mother of two had been addicted to prescription drugs, then made an economic decision.

- "I couldn't afford the pills," Chambers said in an interview at the Southwest Behavioral Health Center in St. George, where she is getting counseling. "It was too much. The only thing I could find was heroin."

[1]SOURCE: Rick Egan, Salt Lake Tribune, October 8, 2010

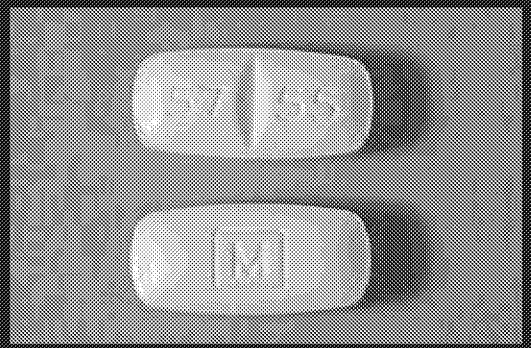
METHADONE

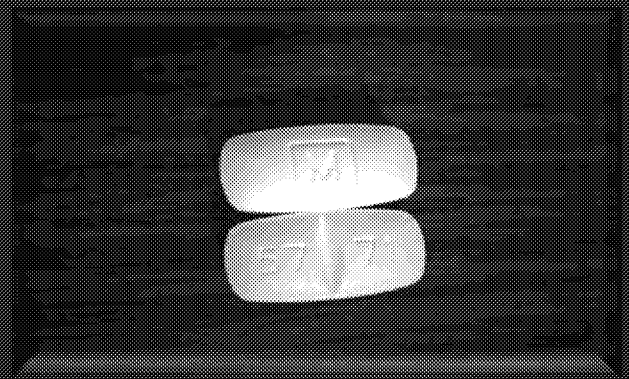
Methadone History

- Methadone was developed in 1937 in Germany as a field painkiller, in anticipation of the potential loss of the raw opium supply for drugs like morphine in the event of war.

- The Controlled Substances Act and corresponding regulations established strict rules for methadone clinics, or Narcotic Treatment Programs (NTPs).

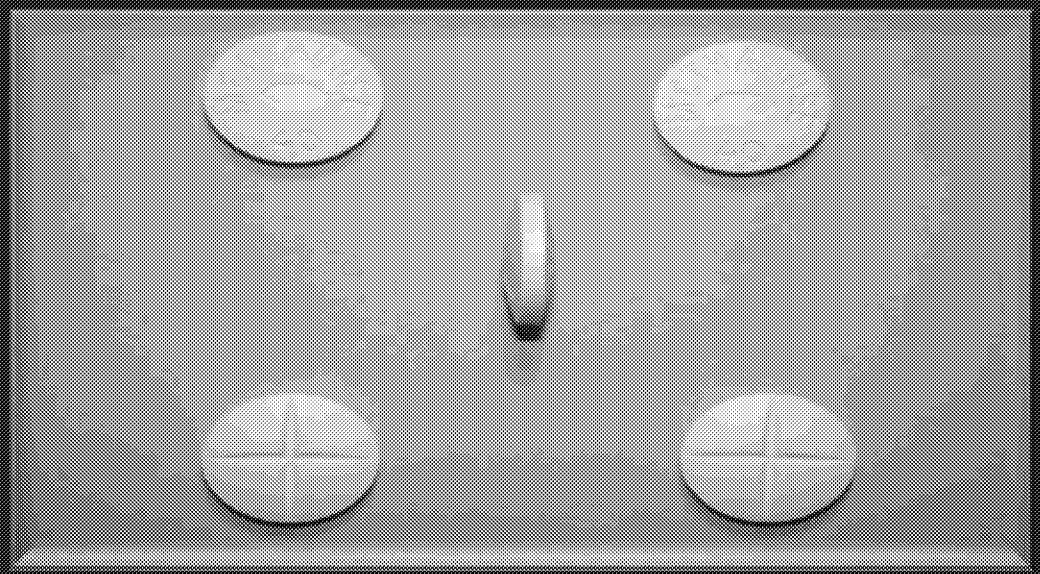
Methadone- 5mg &10mg

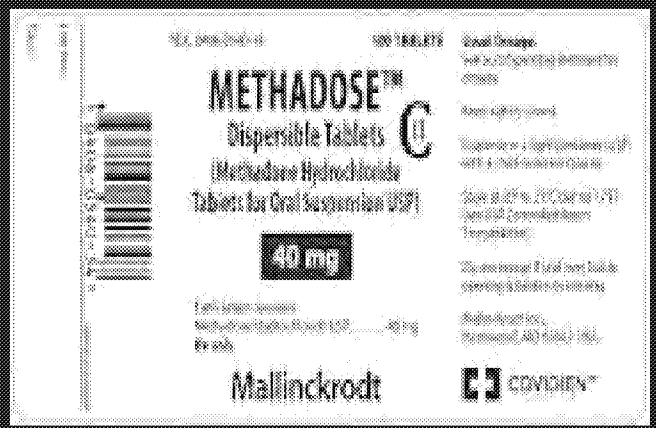




Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg





WHY IS IT ALSO USED AS AN ANALGESIC??????

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?

One Pill can Kill

CE Article: [ACCME/AMA/ANCC] | CE credit for this article

by Jonathan J. Lipman, PharmD

THE METHADONE POISONING "Epidemic"

Increasing use of Methadone as a pain killer may be fueling a disturbing increase in deaths related to this potent drug.

Name _____

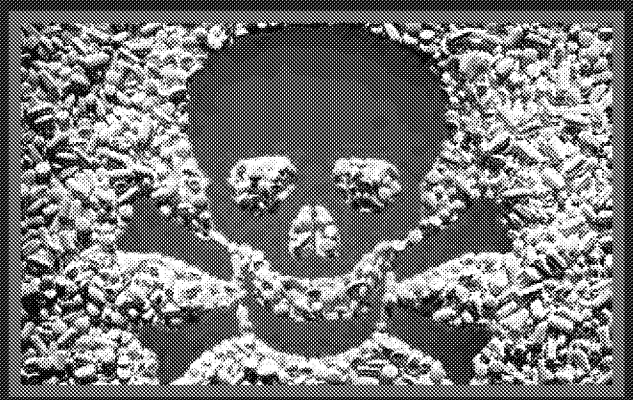
Address _____ Date _____

℞

Death and morbidity associated with methadone treatment has increased dramatically in recent years, largely in the population prescribed this drug for pain control rather than addiction maintenance. Inadvertent overdose is becoming increasingly common, likely in part because the drug's acute pain-relieving effect lasts only 4 to 6 hours, yet it has a very long and variable plasma half-life of 24 to 36 (in some studies 15 to 55) hours, is stored in body tissues, and toxic accumulation occurs with too-frequent consumption. Adverse effects are most common in patients treated with methadone in combination with other drugs. Both cardiac and respiratory systems are vulnerable targets for the drug's toxic actions, and other co-administered drugs can interactively increase the risk of death through a variety of mechanisms including direct central nervous system depression of respiration, idiosyncratic respiratory vulnerabilities, and lethal cardiac arrhythmias. Idiosyncratic factors also play a part in methadone's cardiac toxicity, and risk factors are well characterized, though perhaps not sufficiently widely known and understood by key stakeholders. The recent change in FDA labeling requirements for the drug—and the November 2006 posting of a government warning regarding its use in pain treatment—has not yet reduced morbidity and mortality associated with methadone as reported in the MedWatch database for the first quarter of 2007.

Overdose...Why?

- Patients not taking the drug as directed
- Physicians not properly prescribing the drug
- Non-medical users ingesting with other substances
- Opiate naive



Bluefield Daily Telegraph

William "Randy" Deason, Publisher — Thomas A. Colley, Executive Editor

"Then he answered and spoke to me, saying, This is the word of the LORD to Zerubbabel, saying, Not by might, nor by power, but by my spirit, said the LORD of hosts."

(Zechariah 4:6 ARJV)

Overdose deaths

Prescription drugs take deadly toll in WV

A alarming new study has found that prescription drugs killed more people in West Virginia in 2008 than illegal drugs. According to the report, nine out of the 10 accidental overdose deaths reported in the Mountain State involved prescription drugs. Researchers in a joint state-federal study came to the troubling conclusion after studying 482 accidental overdose autopsy reports, excluding suicides and overdoses, the Associated Press reported.

The report found that one-third of the prescription drugs taken during the fatal incidents were being used as a result of a prescription issued by a doctor within the last 30 days. The report found fewer than one in five of the deaths involved illegal narcotics.

Aron Hall, a Centers for Disease Control Epidemic Intelligence Service Officer for the West Virginia Department of Health and Human Resources, said there is a perception among some citizens that just because narcotics are legal and prescribed drugs, they are somehow safer.

The report found that methadone contributed to one of three deaths, or more than any other prescription drug. However, the report found that only 10 of the overdose victims were enrolled in a methadone clinic for drug-abuse treatment.

The report found that other opioid drugs frequently linked to accidental overdose deaths included hydrocodone and oxycodone. The two narcotics contributed to one in five deaths. Morphine contributed to about one in seven deaths, the report found. Anti-anxiety drugs were found in 43 percent of the deaths.

We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.

While law enforcement officials have been fighting the illegal drug scourge in our region for years, accidental overdose deaths associated with the misuse of prescription narcotics now represents an emerging epidemic for the Mountain State.

The alarming new study from the West Virginia Department of Health and Human Resources should be viewed as a call to action for our community. We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.

We must act now to educate our community. If we fail to act, the number of accidental overdose deaths in the state and the region could continue to rise. It will take a combined effort of public education and law enforcement cooperation to reduce these alarming statistics.

editorials

Rising methadone deaths

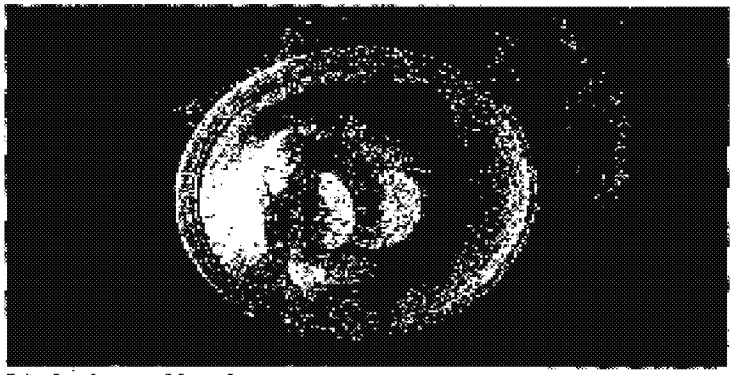
Our view: Baltimore public health officials are trying to find out if treatment for chronic pain sufferers accounts for increase in methadone overdoses

THE JUNE LETTER FROM THE BALTIMORE HEALTH DEpartment alerted physicians, nurses and other providers to a significant increase in methadone-related overdose deaths. The letter from Dr. Laura Herrera, a deputy city health commissioner, raised the possibility that the overdoses involved prescriptions for pain. It was a cautionary reminder that health care providers should educate their patients about the proper use of methadone and the lethal risks of taking extra doses.

Dr. Herrera was right to be concerned: Methadone-overdose deaths of city residents have risen from seven in 1995 to 74 in 2007. In 2007, the last year for which statistics are available, there was a 23 percent increase in such deaths over the previous year. The city deaths coincide with a similarly disturbing fivefold increase in methadone-related deaths nationally between 1999 and 2005. But proving that the use of methadone as a pain reliever caused these deaths isn't easy — no one tracks how many physicians prescribe methadone to relieve chronic pain from cancer or arthritis, for example.

Prescribing methadone has been an accepted form of treatment for chronic pain for some time, according to pain specialists at Johns Hopkins Hospital and the University of Maryland Medical Center. They add that they have seen no methadone-related deaths among their patients. Methadone used for pain treatment is prescribed in pill form; its risk stems from the drug's potency and its lingering presence in the body once its pain-relieving function has ceased. An extra dose could slow down a patient's breathing, resulting in coma or death.

To identify the extent of the problem and the patients most at risk, the city Health Department has reviewed data from the medical examiner's office. It also has asked the quasi-public city agency that oversees drug treatment in Baltimore to cross-check methadone overdose victims against its patient rosters. That's a critical aspect of the review because it could uncover misuse, abuse or diversion of methadone from drug treatment centers. Or it could lend credence to the prevailing view that more training is required for private physicians who prescribe methadone for pain.



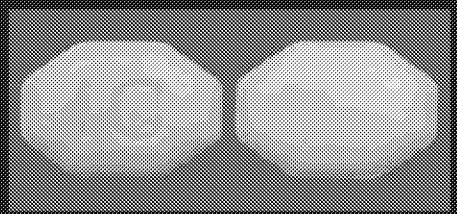
Methadone tablets in a cup. BALTIMORE SUN PHOTO: [illegible]

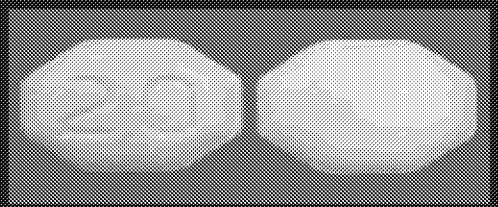
At least 29 states have prescription monitoring programs that would identify indiscriminate prescribing, doctor-shopping and other abuses. A task force established this year in Maryland is studying the possibility of establishing a similar tracking system for methadone and other controlled substances.

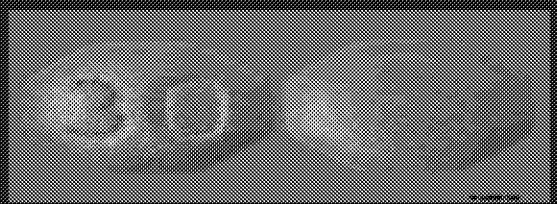
Until then, Dr. Herrera and her colleagues at the Health Department have moved expeditiously and forthrightly to unravel this mystery. The results of their findings are the key to understanding and reversing this disturbing trend.

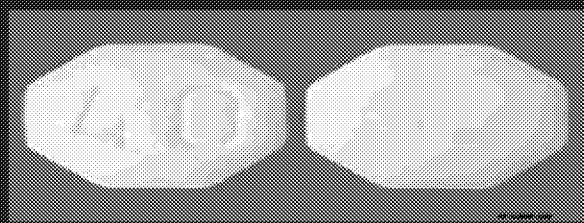
Opana ER (Oxymorphone) (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming more popular and is abused in similar fashion to oxycodone
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: $10.00 – $80.00





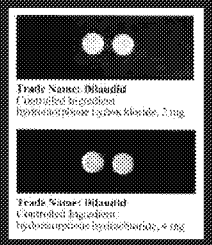




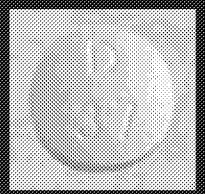
Other Narcotics

Fentanyl

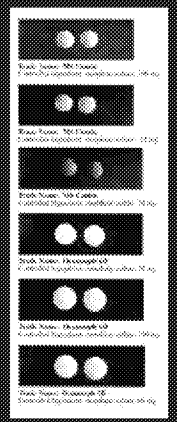
Hydromorphone



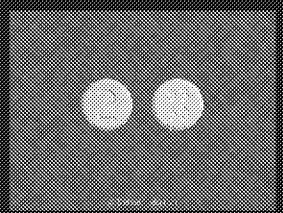
Meperidine



Morphine



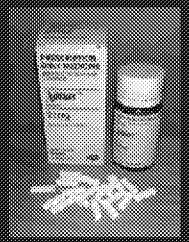
Codeine



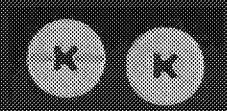
Propoxyphene

Benzodiazepines

Alprazolam

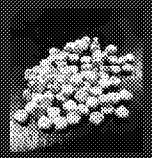


Clonazepam

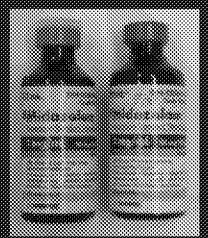


Diazepam

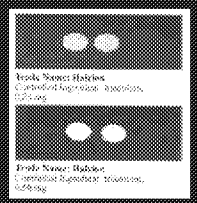
Lorazepam



Midazolam

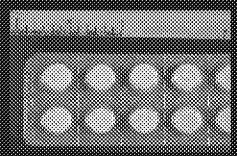


Triazolam

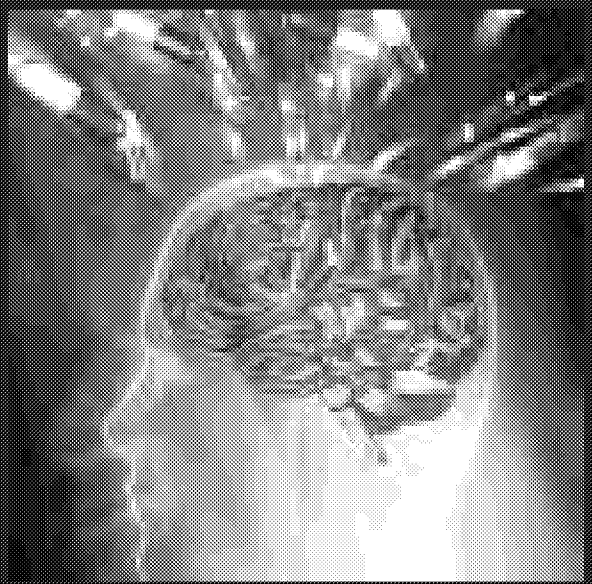


Temazepam

Flunitrazepam



ADHD Drugs:
Ritalin® / Concerta® / Adderall®



ADHD Drugs

- Used legitimately to treat ADHD
- Abuse prevalent among college students; can be snorted, injected or smoked; nicknamed "College Crack"
- $5.00 to $10.00 per pill on illicit market
- Adderall® Abusers are 5 times more likely to also abuse prescription pain relievers, 8 times more likely to abuse Benzodiazepines

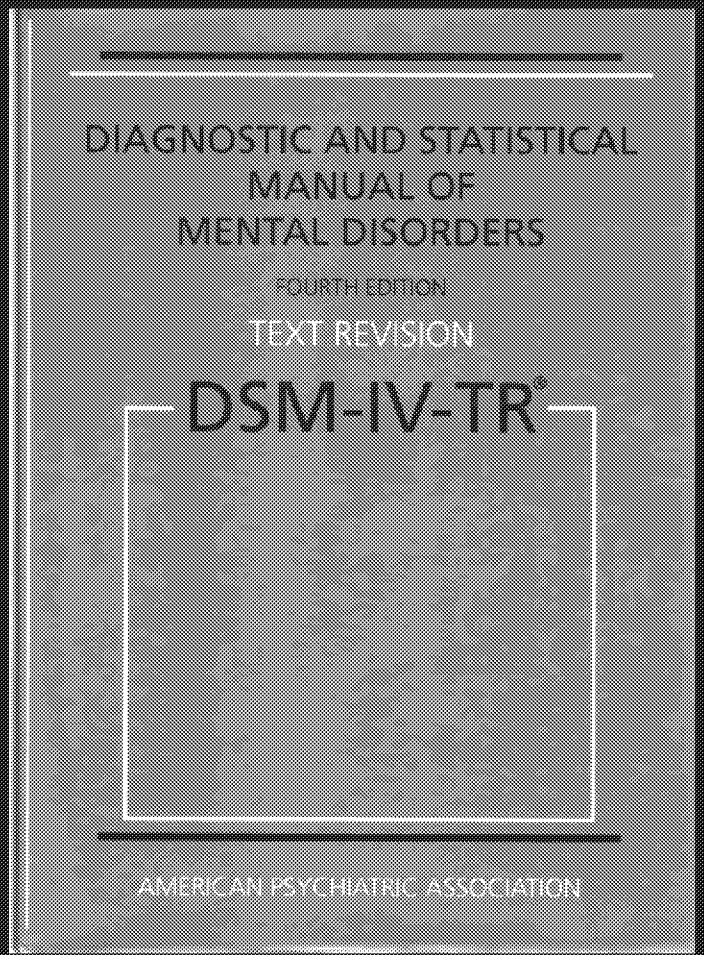
Source: NSDUH Report; Non-Medical Use of Adderall Among Full-Time College Students, published April 2009

ADHD Drugs

- One in eight teens (about 2.7 million) now reports having misused or abused these prescription stimulants at least once in their lifetime
- 9% of teens (about 1.9 million) report having misused or abused these prescription stimulants in the past year (up from 6% in 2008)
- 6% of teens (about 1.3 million) report abuse of these prescription stimulants in the past month (up from 4% in 2008)
- One in four teens (26%) believes that prescription drugs can be used as a study aid
- More than one in five teens (22%) says there is little or no risk in using Ritalin/Adderall without a prescription

Source: 2012 Partnership Attitude Tracking Study, published 4/23/13

Required Reading



Attention-Deficit and Disruptive Behavior Disorders

Attention-Deficit/Hyperactivity Disorder

Diagnostic Features

Some hyperactive-impulsive or inattentive symptoms that cause impairment must have been present before age 7 years, although many individuals are diagnosed after the symptoms have been present for a number of years, especially in the case of individuals with the Predominantly Inattentive Type (Criterion B)

A1c). There may be frequent shifts from one uncompleted activity to another. Individuals diagnosed with this disorder may begin a task, move on to another, then turn to yet something else, prior to completing any one task. They often do not follow through on requests or instructions and fail to complete schoolwork, chores, or other duties (Criterion A1d). Failure to complete tasks should be considered in making this diagnosis only if it is due to inattention as opposed to other possible reasons (e.g., failure to understand instructions, defiance). These individuals often have difficulties organizing tasks and activities (Criterion A1e). Tasks that require sustained mental effort are experienced as unpleasant and markedly aversive. As a result, these individuals typically avoid or have a strong dislike for activities that demand sustained self-application and mental effort or that require organizational demands or close concentration (e.g., homework or paperwork) (Criterion A1f). This avoidance must be due to the person's difficulties with attention and not due to a primary oppositional attitude, although secondary oppositionalism may also occur. Work habits are often disorganized and the materials necessary for doing the task are often scattered, lost, or carelessly handled and damaged (Criterion A1g). Individuals with this disor-

- Fails to give close attention to details...make careless mistakes in schoolwork, work
- Difficulty sustaining attention in tasks
- Does not seem to listen when spoken to
- Does not follow through on instructions
- Difficulty organizing tasks
- Often loses things necessary for tasks
- Easily distracted
- Forgetful

(h) is often easily distracted by extraneous stimuli
(i) is often forgetful in daily activities

(2) six (*or more*) of the following symptoms of **hyperactivity-impulsivity** have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:

Hyperactivity
(a) often fidgets with hands or feet or squirms in seat
(b) often leaves seat in classroom or in other situations in which remaining

- Fidgets
- Can't remain seated
- Restlessness
- Difficulty awaiting turn
- Often interrupts or intrudes

B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.

C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).

There are no laboratory tests, neurologocal assessments, or attentional assessments that have been established as diagnostic in the clinical assessment of Attention-Deficit/Hyperactivity Disorder

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with successful treatment. On average, individuals with Attention-Deficit/Hyperactivity Disorder obtain less schooling than their peers and have poorer vocational achievement. Also, on average, intellectual level, as assessed by individual IQ tests, is several points lower in children with this disorder compared with peers. At the same time, great variability in IQ is evidenced: individuals with Attention-Deficit/Hyperactivity Disorder may show intellectual development in the above-average or gifted range. In its severe form, the disorder is markedly impairing, affecting social, familial, and scholastic adjustment. All three subtypes are associated with significant impairment. Academic deficits and school-related problems tend to be most pronounced in the types marked by inattention (Predominantly Inattentive and Combined Types), whereas peer rejection and, to a lesser extent, accidental injury are most salient in the types marked by hyperactivity and impulsivity (Predominantly Hyperactive-Impulsive and Combined Types). Individuals with the Predominantly Inattentive Type tend to be socially passive and appear to be neglected, rather than rejected, by peers.

A substantial proportion (approximately half) of clinic-referred children with Attention-Deficit/Hyperactivity Disorder also have Oppositional Defiant Disorder or Conduct Disorder. The rates of co-occurrence of Attention-Deficit/Hyperactivity Disorder with these other Disruptive Behavior Disorders are higher than with other mental disorders, and this co-occurrence is most likely in the two subtypes marked by hyperactivity-impulsivity (Hyperactive-Impulsive and Combined Types). Other associated disorders include Mood Disorders, Anxiety Disorders, Learning Disorders, and Communication Disorders in children with Attention-Deficit/Hyperactivity Disorder. Although Attention-Deficit/Hyperactivity Disorder appears in at least 50% of clinic-referred individuals with Tourette's Disorder, most individuals with Attention-Deficit/Hyperactivity Disorder do not have accompanying Tourette's Disorder. When the two disorders coexist, the onset of the Attention-Deficit/Hyperactivity Disorder often precedes the onset of the Tourette's Disorder.

There may be a history of child abuse or neglect, multiple foster placements, neurotoxin exposure (e.g., lead poisoning), infections (e.g., encephalitis), drug exposure in utero, or Mental Retardation. Although low birth weight may sometimes be associated with Attention-Deficit/Hyperactivity Disorder, most children with low birth weight do not develop Attention-Deficit/Hyperactivity Disorder, and most children with Attention-Deficit/Hyperactivity Disorder do not have a history of low birth weight.

Associated laboratory findings. There are no laboratory tests, neurological assessments, or attentional assessments that have been established as diagnostic in the clin-

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There are no specific physical features associated with Attention-Deficit/Hyperactivity Disorder, although minor physical anomalies (e.g., hypertelorism, highly arched palate, low-set ears) may occur at a higher rate than in the general population. There may also be a higher rate of accidental physical injury.

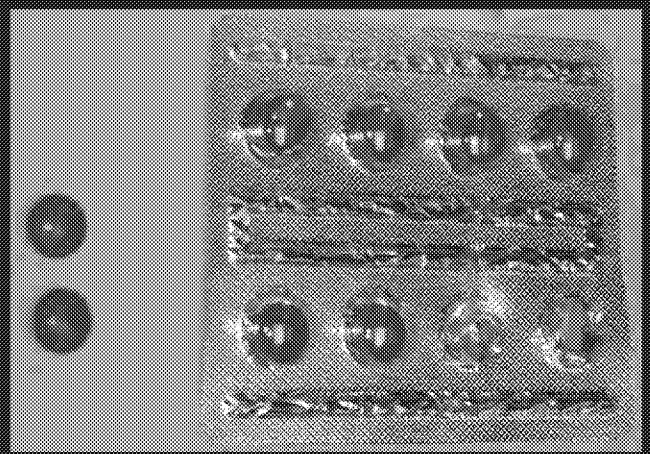
Specific Culture, Age, and Gender Features

Attention-Deficit/Hyperactivity Disorder is known to occur in various cultures, with variations in reported prevalence among Western countries probably arising more from different diagnostic practices than from differences in clinical presentation.

It is difficult to establish this diagnosis in children younger than age 4 or 5 years, because their characteristic behavior is much more variable than that of older children and may include features that are similar to symptoms of Attention-Deficit/Hyperactivity Disorder. Furthermore, symptoms of inattention in toddlers or preschool children are often not readily observed because young children typically experience few demands for sustained attention. However, even the attention of toddlers can be held in a variety of situations (e.g., the average 2- or 3-year-old child can typically sit with an adult looking through picture books). Young children with Attention-Deficit/Hyperactivity Disorder move excessively and typically are difficult to contain. Inquiring about a wide variety of behaviors in a young child may be helpful in ensuring that a full clinical picture has been obtained. Substantial impairment has been demonstrated in preschool-age children with Attention-Deficit/Hyperactivity Disorder. In school-age children, symptoms of inattention affect classroom work and academic performance. Impulsive symptoms may also lead to the breaking of familial, interpersonal, and educational rules. Symptoms of Attention-Deficit/Hyperactivity Disorder are typically at their most prominent during the elementary grades. As children mature, symptoms usually become less conspicuous. By late childhood and early adolescence, signs of excessive gross motor activity (e.g., excessive running and climbing, not remaining seated) are less common, and hyperactivity symptoms may be confined to fidgetiness or an inner feeling of jitteriness or restlessness. In adulthood, restlessness may lead to difficulty in participating in sedentary activities and to avoiding pastimes or occupations that provide limited opportunity for spontaneous movement (e.g., desk jobs). Social dysfunction in adults appears to be especially likely in those who had additional concurrent diagnoses in childhood. Caution should be exercised in making the diagnosis of Attention-Deficit/Hyperactivity Disorder in adults solely on the basis of the adult's recall of being inattentive or hyperactive as a child, because the validity of such retrospective data is often problematic. Although supporting information may not always be available, corroborating information from other informants (including prior school records) is helpful for improving the accuracy of the diagnosis.

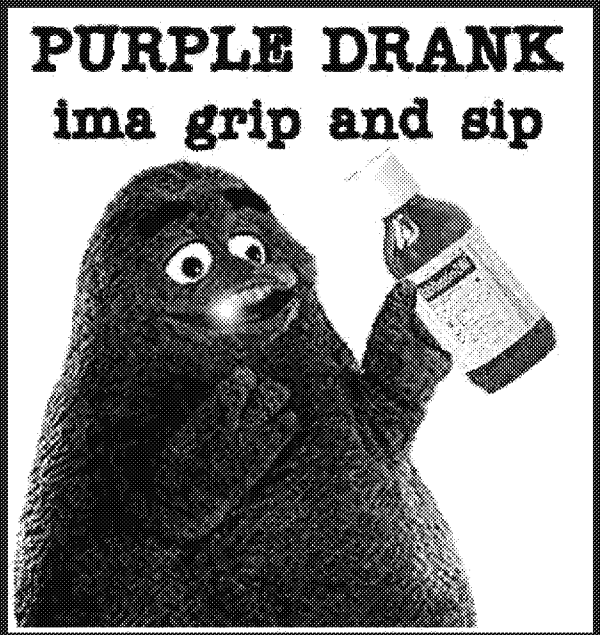
Dextromethorphan (DXM)

- Cough suppressant in over 125 OTC medications (e.g., Robitussin and Coricidin)
- Bulk form on the Internet
- At high doses, has Ketamine- and PCP-like effects
- Produces physical and psychological dependence
- Deaths associated with DXM abuse



Cough Syrup Cocktails

- "Syrup and Soda"
- "Seven and Syrup"
- "Purple Drank"



Tramadol – Notice of Proposed Rule Making

- On November 4, 2013 prepared a "Notice of Proposed Rulemaking" to schedule Tramadol into schedule IV
- Open for 60 days of Public Comment

Federal Register / Vol. 78, No. 211 / Monday, November 4, 2013 / Proposed Rules 65923

essential to, or that yields information that is essential in, the restoration or continuation of a bodily function important to the continuation of human life.

Meaningful disruption means a change in production that is reasonably likely to lead to a reduction in the supply of a biological product by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

Dated: October 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-25956 Filed 11-1-13; 11:15 am]

BILLING CODE 4160-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–351]

Schedules of Controlled Substances: Placement of Tramadol into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to place the substance 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms including tramadol if the term "isomers" includes the optical and geometric isomers) into Schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (HHS) and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle tramadol.

DATES: Interested persons may file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before January 6, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)." 21 CFR 1308.41, may file a request for hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and 1316.47. Requests for hearing, notice of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before December 4, 2013.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–351" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. An electronic copy of this document and supplemental information to this proposed rule are also available at the *http://www.regulations.gov* Web site for easy reference. Paper comments that duplicate electronic submissions are not necessary. All comments submitted to *http://www.regulations.gov* will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 598–6812.

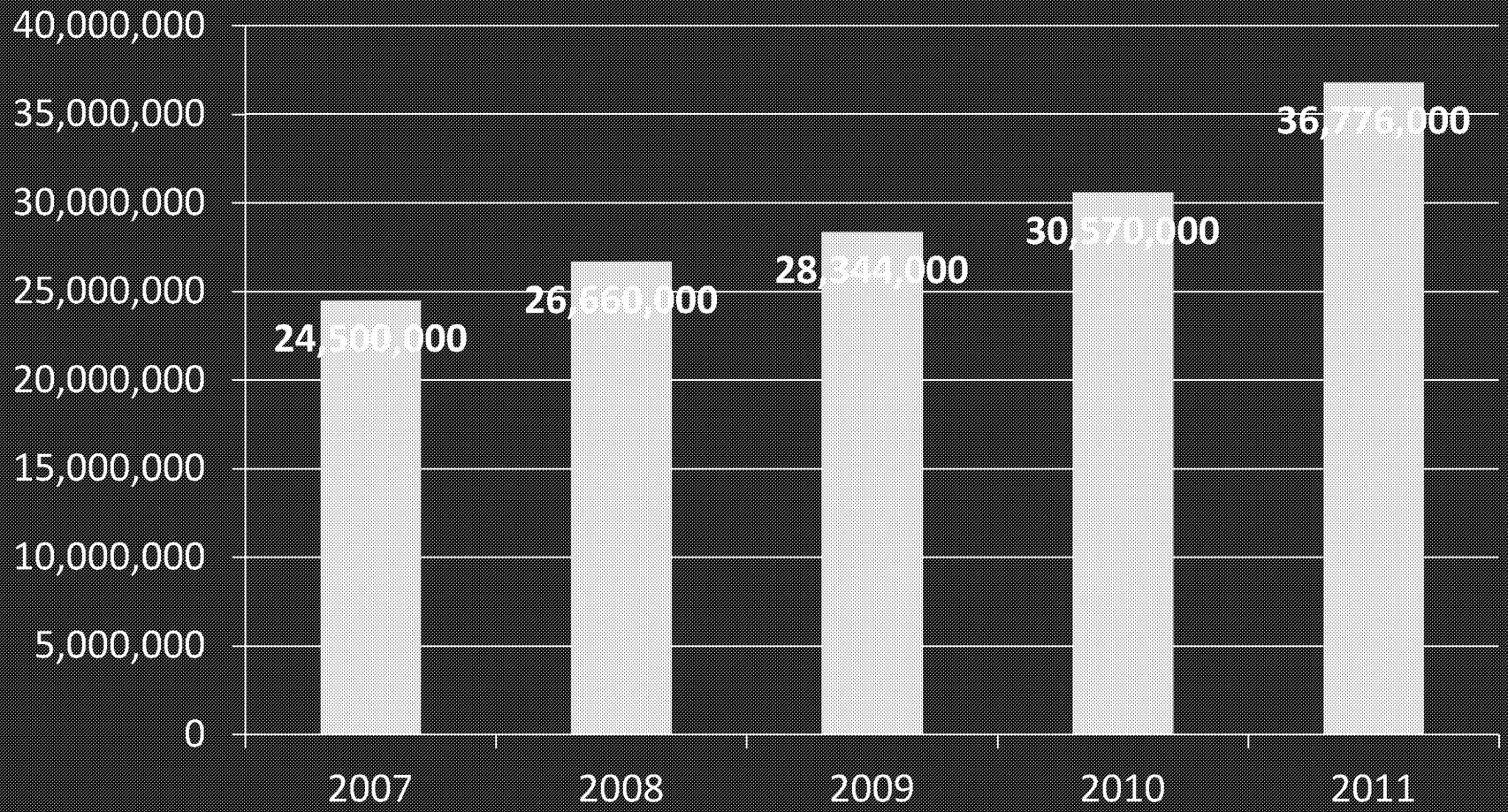
SUPPLEMENTARY INFORMATION: *Posting of Public Comments:* Please note that comments received in response to this NPRM are considered part of the public record and will be made available for public inspection and posted at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made public, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want to be made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available.

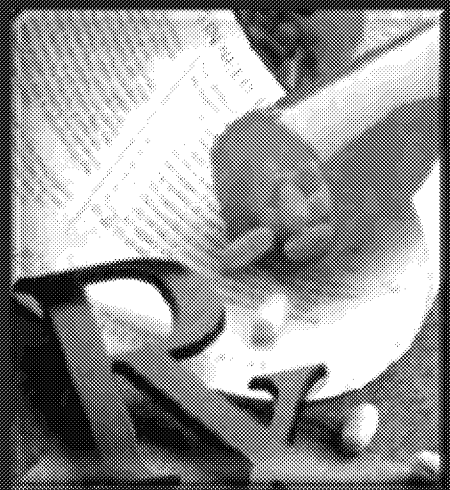
Comments containing personal identifying information and confidential business information identified and located as set forth above will be made available in redacted form. The Freedom of Information Act (FOIA) applies to all comments received. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the **FOR FURTHER INFORMATION CONTACT** paragraph, above.

Tramadol Prescriptions



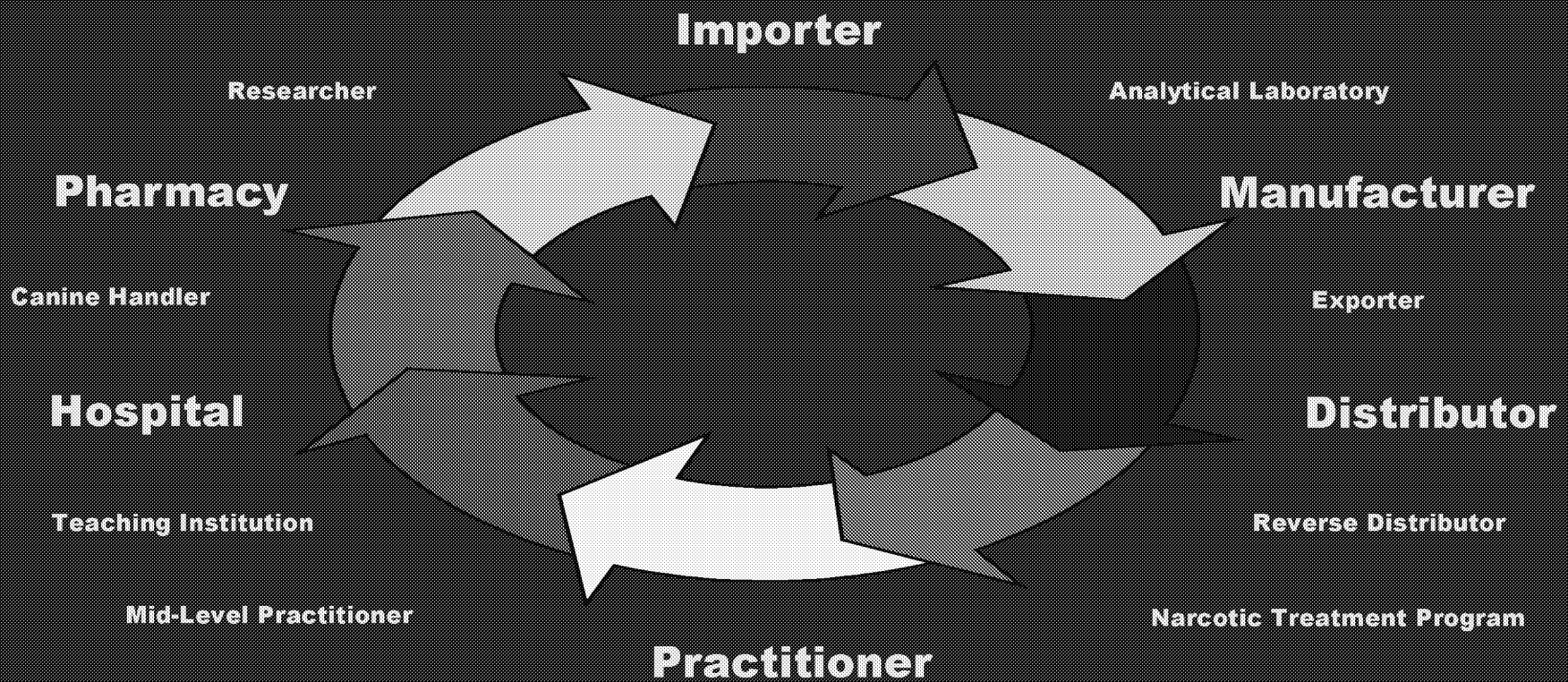
Source: IMS Health National Prescription Audit Plus downloaded 6/5/2012

THE CSA: CHECKS & BALANCES



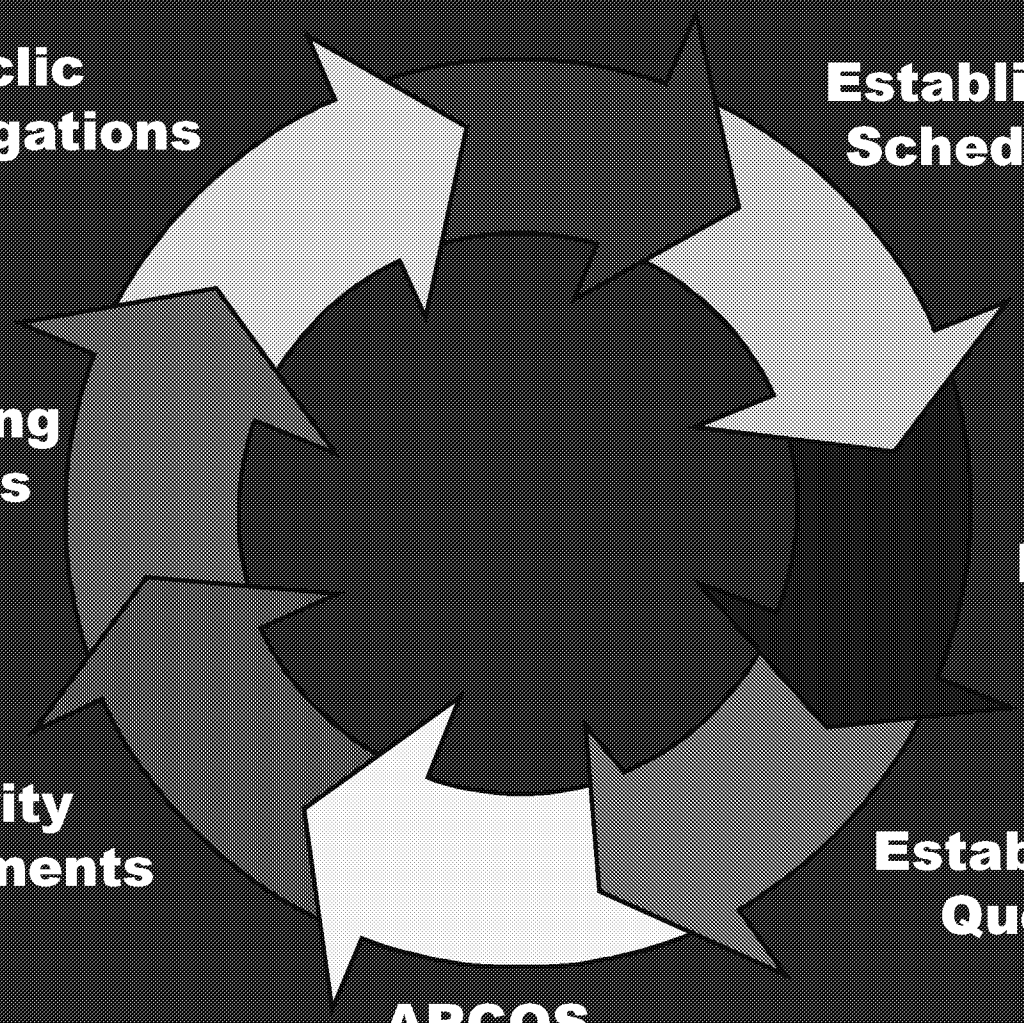
U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control

The CSA's Closed System of Distribution

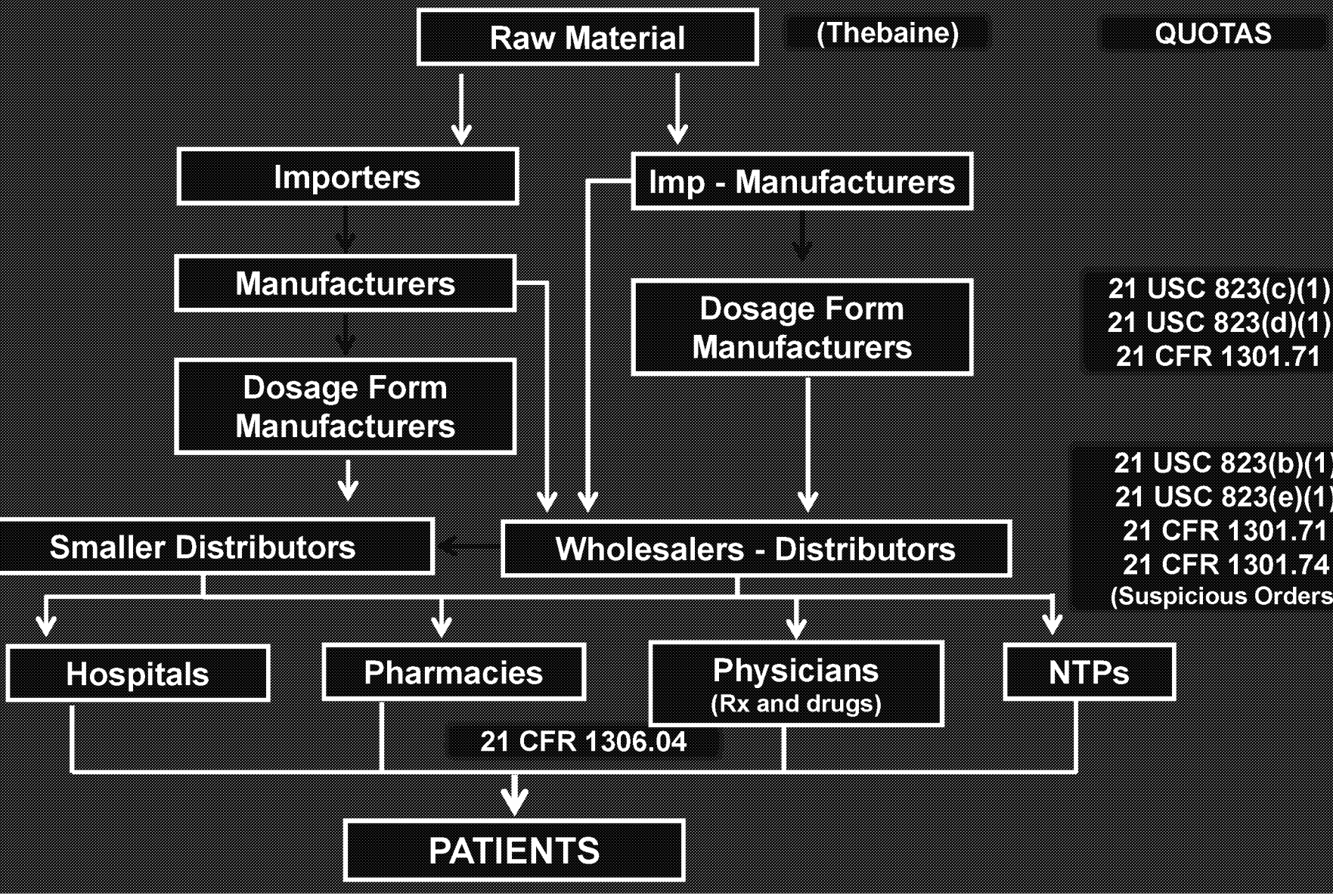


1,469,821 DEA REGISTRANTS

The CSA's Closed System of Distribution



The Flow of Pharmaceuticals



Checks and Balances of the CSA and the Regulatory Scheme

- Distributors of controlled substances

"The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances…Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." (21 CFR §1301.74)

Checks and Balances Under the CSA

- Practitioners

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice." (21 CFR §1306.04(a))

United States v Moore 423 US 122 (1975)

Checks and Balances Under the CSA

- Pharmacists – The Last Line of Defense

"The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." (21 CFR §1306.04(a))

What can happen when these checks and balances collapse ?

Large-Scale Diversion

- In 2009, the average purchase for all oxycodone products for all pharmacies in US – 63,294 d.u.
- In 2010, the average was – 69,449 d.u.
- In 2009, the average purchase for all oxycodone products for the top 100 pharmacies in Florida – 1,226,460 d.u.
- In 2010, the average was – 1,261,908 d.u.

Large-Scale Diversion

- In 2011, the average purchase for all oxycodone products for all pharmacies in US – 74,706 d.u.
- In 2012, the average was – 73,434 d.u.
- In 2011, the average purchase for all oxycodone products for the top 100 pharmacies in Tennessee – 490,781 d.u.
- In 2012, the average was – 466,061 d.u.

WHERE PEOPLE ARE GETTING THEIR DRUGS

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control

Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family….For Free!!

The Medicine Cabinet: The Problem of Easy Access

So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules

National Take Back Initiatives

Over 3.4 million pounds (1,733 tons) collected

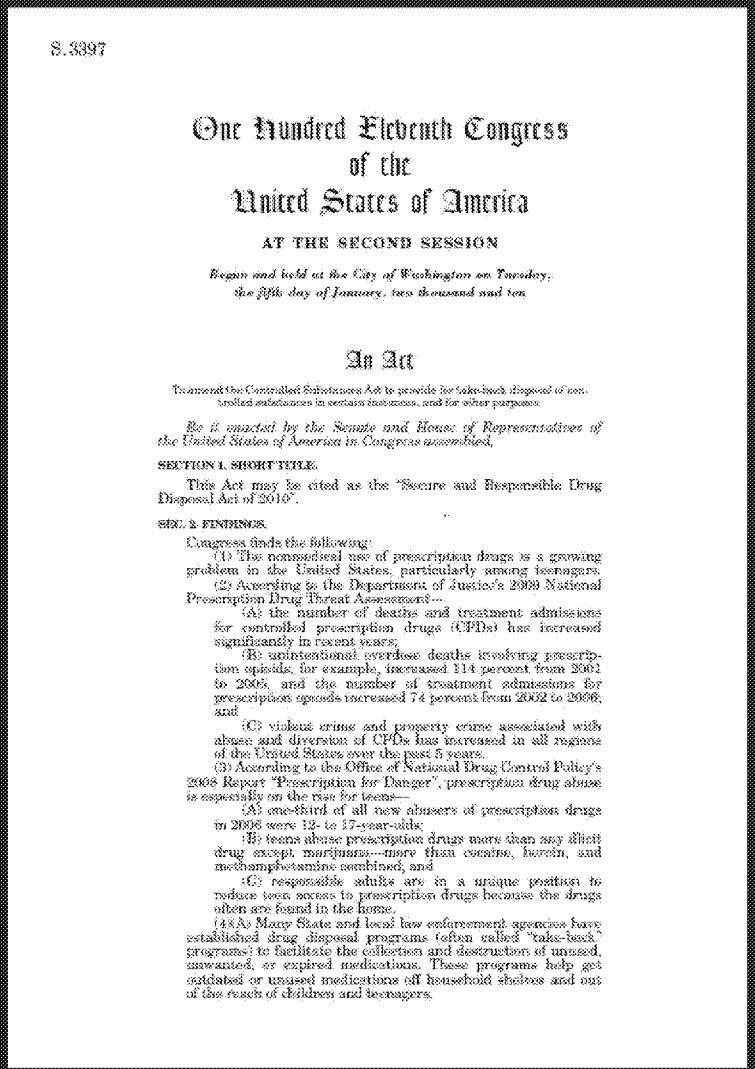
- September 30, 2010: 242,383 pounds (121 tons)
- April 30, 2011: 376,593 pounds (188 tons)
- October 29, 2011: 377,086 pounds (189 tons)
- April 28, 2012: 552,161 pounds (276 tons)
- September 29, 2012: 488,395 pounds (244 tons)
- April 27, 2013: 742,497 pounds (371 tons)
- October 26, 2013: 647,211 pounds (324 tons)

Take-Back Event

Boxed, Sealed, Counted, Weighed, Consolidated, Secured, and Incinerated

Looking to the Future: The Secure and Responsible Drug Disposal Act of 2010

- On October 12, 2010, the President signed the "***Secure and Responsible Drug Disposal Act of 2010***."
- This Act allows DEA to draft new regulations which permits ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.



S. 3397

One Hundred Eleventh Congress
of the
United States of America
AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the fifth day of January, two thousand and ten

An Act

To amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Secure and Responsible Drug Disposal Act of 2010".

SEC. 2. FINDINGS.

Congress finds the following:

(1) The nonmedical use of prescription drugs is a growing problem in the United States, particularly among teenagers.

(2) According to the Department of Justice's 2009 National Prescription Drug Threat Assessment—

(A) the number of deaths and treatment admissions for controlled prescription drugs (CPDs) has increased significantly in recent years;

(B) unintentional overdose deaths involving prescription opioids, for example, increased 114 percent from 2001 to 2005, and the number of treatment admissions for prescription opioids increased 74 percent from 2002 to 2006; and

(C) violent crime and property crime associated with abuse and diversion of CPDs has increased in all regions of the United States over the past 5 years.

(3) According to the Office of National Drug Control Policy's 2008 Report "Prescription for Danger", prescription drug abuse is especially on the rise for teens—

(A) one-third of all new abusers of prescription drugs in 2006 were 12- to 17-year-olds;

(B) teens abuse prescription drugs more than any illicit drug except marijuana—more than cocaine, heroin, and methamphetamine combined; and

(C) responsible adults are in a unique position to reduce teen access to prescription drugs because the drugs often are found in the home.

(4)(A) Many State and local law enforcement agencies have established drug disposal programs (often called "take-back" programs) to facilitate the collection and destruction of unused, unwanted, or expired medications. These programs help get outdated or unused medications off household shelves and out of the reach of children and teenagers.

The Secure and Responsible Drug Disposal Act of 2010

As DEA worked to promulgate regulations to implement the Act, we have been required to consider:

- Public health and safety
- Ease and cost of program implementation
- Participation by various communities
- Diversion Control